

K823177 SMEC BALLOON SYSTEMDec 15, 1982
50 days to decisionK823177 · Product code: **DSP** · CardiovascularSource: <https://www.510kdatabase.net/k823177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Oct 26, 1982
Decision date	Dec 15, 1982
Days to decision	50 days
Third-party review	No

APPLICANT

Company	Smec, Inc.
Location	Mchenry, IL, US
510(k) history	7 submissions · 7 cleared · 1980-1985

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k823177/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 8, 2026